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Angie Hoang

May 23, 2007

Attorney Docket No. 10002-701.406

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Inventor: Mark A. Reiley

Application No.: 10/657,837

Filed: September 9, 2003

Title: FACET ARTHROPLASTY
DEVICES AND METHODS

Confirmation No.: 1759

Group Art Unit: 3738

Examiner: David J. Isabella

Customer No.: 66854

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450
Sir:

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith are the following documents in the above-identified application:

- (1) This Transmittal Letter; and
- (2) Appeal Brief

☒ Please charge the fee required under 37 C.F.R. 41.20(b)(2) of \$250.00 to Deposit Account No. 50-4050. Please also deduct or credit to said Deposit Account any other Fees attendant with this matter.

Respectfully submitted,

Dated: May 23, 2007

By:

Douglas C. Limbach
Douglas C. Limbach, Reg. No. 35,249

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APPEAL BRIEF

Attorney Docket No. 10002-701.406

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application:

Inventor: Mark A. Reiley
Application No.: 10/657,837
Filed: September 9, 2003
Title: FACET ARTHROPLASTY
DEVICES AND METHODS

Confirmation No.: 1759
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Group Art Unit: 3738
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APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants submit this brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Final Rejection mailed August 23, 2006. Appellants' Notice of Appeal was filed March 23, 2007, along with a Petition to Revive filed the same day. If the Petition to Revive is granted, this Appeal Brief is timely filed.

Unless a check is submitted herewith for the fee required under 37 C.F.R. 41.20(b)(2), please charge said fee to Deposit account No. 50-4050.

I. REAL PARTY IN INTEREST

The real party in interest is Archus Orthopedics, Inc. (Assignee) by virtue of an assignment of the parent US Patent 6,610,091 from the inventor to Total Facet Technologies (recorded by the Assignment Branch of the US Patent and Trademark Office at Reel/Frame 013749/0176 on 6/20/03) and from Total Facet Technologies to Archus Orthopedics, Inc. (recorded by the Assignment Branch of the US Patent and Trademark Office at Reel/Frame 013755/0073 on 6/23/03).

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II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-29 are currently pending. Of these, claims 3, 7, 10, 20-22 have been withdrawn as being directed to a non-elected species/invention pursuant to restriction and election of species requirements dated July 26, 2004, leaving claims 1, 2, 4-6, 8, 9, 11-19 and 23-29 for prosecution on the merits. Claims 1, 2, 4-6, 8, 9, 11-17 and 19 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Zang et al. US 5,314,486 (hereinafter "Zang"). Claims 5, 6 and 18 stand rejected under 35 U.S.C. § 103(a) over Zang in view of Johnson et al. US 5,609,641 (hereinafter "Johnson"). While the cover page of the Final Office Action states that claims 23-29 are rejected, the recitation of the § 102 and § 103 rejections in the Final Office Action do not include claims 23-29. The rejections of claims 1, 2, 4-6, 8, 9, 11-19 and 23-29 are appealed.

IV. STATUS OF AMENDMENTS

Appellants have submitted no amendments after the final rejection. All amendments prior to the close of prosecution on the merits have been entered. Appellant never received any Advisory Action or other response to Appellant's after-Final Amendment and Response dated December 18, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a prosthesis to replace all or a portion of a natural facet joint on a vertebra including a fastening element adapted to be removably attached to the vertebra; a structure removably attached to the fastening element; and a prosthetic facet joint articulating surface dimensioned to replace all or a portion of a natural facet joint on the vertebra wherein the prosthetic facet joint articulating surface removably attaches to the structure. Fastening elements are shown and discussed at least at page 11, lines 25-31; page 13, lines 8-23; page 18, lines 12-23; page 22, line 35 to page 23, line 6; page 27, lines 16-35; page 30, lines 6-14; page 31, line 33 to page 32, line 14; and Figures 2 (element 310, 310a), 11 (elements 520a, 520b, 515), 12 (elements 330, 515), 21 (elements 715, 720), 24 (element 720), 25 (element 720), 32 (element 37), 33 (element 37), 35, 37-39 (element 65), 41 (element 34) and 42 (element 330). Structures removably attached to fastening elements are shown and discussed at least at page 12, lines 7-8; page 13, lines 13-16; page 17, line 34 to page 18, line 23; page 22, line 25 to page 24, line 25; page 29, line 31 to page 30, line 16; page

31, line 29 to page 32, line 24; page 34, line 24 to page 35, line 27; and Figures 2 (element 315), 11-12 (element 505), 21-25 (element 705) and 29-42 (elements 28, 38, 58, 60). Prosthetic facet joint articulating surfaces dimensioned to replace all or a portion of a natural facet join on the vertebra that are removably attached to structures removably attached to a fastening element are shown and described at least at page 13, lines 2-7; page 18, line 24 to page 19, line 18; page 24, line 26 to page 25, line 16; page 30, lines 16-29; page 32, lines 15-24; page 36, lines 22-30; and Figures 2 (element 325), 11-12 (elements 510, 510b), 21 (element 710), 23-25 (element 710), and 29-42 (elements 30, 40, 66).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 1, 2, 4-6, 8, 9, 11, 12, 16-17, 19, 23-25, 28 and 29 are patentable under 35 U.S.C. § 102(b) over Zang.
2. Whether claim 13 is patentable under 35 U.S.C. § 102(b) over Zang.
3. Whether claim 14 is patentable under 35 U.S.C. § 102(b) over Zang.
4. Whether claim 15 is patentable under 35 U.S.C. § 102(b) over Zang.
5. Whether claim 26 is patentable under 35 U.S.C. § 102(b) over Zang.
6. Whether claim 27 is patentable under 35 U.S.C. § 102(b) over Zang.
7. Whether claims 5, 6 and 18 are patentable under 35 U.S.C. § 103(a) over Zang in view of Johnson.

VII. ARGUMENT

Appellants respectfully submit that claims 1, 2, 4-6, 8, 9, 11-19 and 23-29 are in proper form and are patentable over the prior art of record.

The Legal Standards for Novelty and Obviousness

During patent examination the PTO bears the initial burden of presenting a prima facie case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992).

To establish a prima facie case showing lack of novelty, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

To establish a prima facie case of obviousness, it is necessary for the examiner to present evidence that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Ex parte Levengood, 28 USPQ2d 1300, 1301 (Bd. Pat. App. & Int. 1993). Such evidence may be in the form of a teaching, suggestion or motivation in the applied prior art, or in the form of generally available knowledge. KSR Int'l Co. v. Teleflex Inc., 550 U.S. ___ (2007). Leapfrog v. Fisher-Price, (Fed. Cir. 2007). "[I]n formulating a rejection under 35 U.S.C. 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed."

See Preliminary USPTO Obviousness Examination Instructions in Post-KSR Memorandum from Deputy Commissioner for Patent Operations Margaret A. Focarino, May 3, 2007. "To facilitate review, [the apparent reasons for combining prior art] should be made explicit." Id. Failure to meet the burden of establishing a prima facie case of obviousness requires overturning the obviousness rejection. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed.Cir. 1993).

The Final Office Action Failed to Address All Claims

As stated above, while the cover page of the Final Office Action states that claims 23-29 are rejected, the Final Office Action does not specifically address the statutory basis of the rejection of claims 23-29. (See Final Office Action at pp. 3-4). Furthermore, while the Final Office Action does mention claims 23, and 26-29 in the discussion under the § 102(b) rejection, there is no mention of claim 24 at all. Nonetheless, claims 23-29 remain under consideration in this application, and Appellant will therefore address the patentability of claims 23-29 in addition to arguing the patentability of the claims the Examiner actually did consider.

Claims 1, 2, 4-6, 8, 9, 11, 12, 16-17, 19, 23-25, 28 And 29 Are Patentable Over Zang

Claim 1 recites a prosthesis to replace all or a portion of a natural facet joint on a vertebra, comprising: a fastening element adapted to be removably attached to the vertebra; a structure

removably attached to the fastening element; and a prosthetic facet joint articulating surface dimensioned to replace all or a portion of a natural facet joint on the vertebra wherein the prosthetic facet joint articulating surface removably attaches to the structure. Zang, on the other hand, discloses a metatarso-phalangeal joint prosthesis. Zang does not show a fastening element adapted to be removably attached to the vertebra or a prosthetic facet joint articulating surface dimensioned to replace all or a portion of a natural facet joint on the vertebra that is removably attached to a structure that is itself removably attached to the fastening element, as recited in claim 1. In constructing the argument supporting his rejection, the Examiner arbitrarily chose to ignore these key claim recitations to reach the remarkable conclusion that the Zang prosthesis is capable of replacing all or a portion of a vertebral facet joint. (Final Office Action, page 3.) The Examiner, however, has not pointed to any controlling authority for his position that the specific structural limitations of "adapted to be removably attached to the vertebra" and "dimensioned to replace all or a portion of a natural facet joint on the vertebra" may be ignored when construing the scope of this claim.

The Examiner appears to believe that Applicant's specification must recite the specific dimensions of a vertebral facet joint prosthesis in order for Applicant's claim to define over Zang's metatarso-phalangeal joint prosthesis. (Final Office Action, page 2). Once again, the Examiner has not cited any legal support for this requirement. Applicant's specification meets the disclosure requirements of the first paragraph of 35 U.S.C. § 112, and Applicant's claims meet the definiteness requirements of the second paragraph of § 112. A skilled artisan would understand the meaning and scope of Applicant's claims after reading the specification, a fact tacitly admitted by the Examiner since there are no § 112 rejections or objections in the Examiner's action.

For these reasons, claim 1, and claims 2, 4-6, 8, 9, 11, 12, 16-17, 19, 23-25, 28 and 29 which depend from it, are patentable over Zang under § 102(b).

Claim 13 Is Patentable Over Zang

Claim 13 depends from claim 1 and is therefore patentable over Zang for the reasons stated above with respect to claim 1. In addition, claim 13 further limits claim 1 by requiring that the prosthetic facet joint articulating surface be adapted and configured to articulate with a portion of a facet joint of an adjoining vertebra. The Final Office Action never directly addresses this limitation. At most, the Examiner asserts that the Zang foot bone prosthesis is "structurally similar" to the

claimed vertebral facet joint prosthesis "and therefor[e] remains capable of providing the same function" as the claimed invention. (Final Office Action at pp. 2-3). The Examiner never points to any support in Zang or elsewhere in the prior art that a foot bone prosthesis fixed to one vertebra would be able to articulate with a portion of a facet joint of an adjoining vertebra, as required by claim 13. For these reasons, claim 13 is patentable over Zang under § 102(b).

Claim 14 Is Patentable Over Zang

Claim 14 depends from claim 1 and is therefore patentable over Zang for the reasons stated above with respect to claim 1. In addition, claim 14 further limits claim 1 by requiring that the prosthetic facet joint articulating surface be adapted and configured to replace a caudal portion of a natural facet joint. Once again, the Final Office Action never directly addresses this limitation. At most, the Examiner asserts that the Zang foot bone prosthesis is "structurally similar" to the claimed vertebral facet joint prosthesis "and therefor[e] remains capable of providing the same function" as the claimed invention. The Examiner never points to any support in Zang or elsewhere in the prior art that a foot bone prosthesis fixed to a vertebra would be able to replace a caudal portion of a natural facet joint, as required by claim 14. For these reasons, claim 14 is patentable over Zang under § 102(b).

Claim 15 Is Patentable Over Zang

Claim 15 depends from claim 1 and is therefore patentable over Zang for the reasons stated above with respect to claim 1. In addition, claim 15 further limits claim 1 by requiring that the prosthetic facet joint articulating surface be adapted and configured to replace a caudal portion of a natural facet joint and articulate with a cephalad portion of a facet joint of an adjoining vertebra. Once again, the Final Office Action never directly addresses these limitations. At most, the Examiner asserts that the Zang foot bone prosthesis is "structurally similar" to the claimed vertebral facet joint prosthesis "and therefor[e] remains capable of providing the same function" as the claimed invention. The Examiner never points to any support in Zang or elsewhere in the prior art that a foot bone prosthesis fixed to one vertebra would be able to replace a caudal portion of a natural facet joint, and would be able to articulate with a cephalad portion of a facet joint of an adjoining vertebra, as required by claim 15. For these reasons, claim 15 is patentable over Zang under § 102(b).

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Claim 26 Is Patentable Over Zang

Claim 26 depends from claim 1 and is therefore patentable over Zang for the reasons stated above with respect to claim 1. In addition, claim 26 further limits claim 1 by requiring that the prosthetic facet joint articulating surface be adapted and configured to replace a cephalad portion of a natural facet joint. Once again, the Final Office Action never directly addresses this limitation. At most, the Examiner asserts that the Zang foot bone prosthesis is "structurally similar" to the claimed vertebral facet joint prosthesis "and therefor[e] remains capable of providing the same function" as the claimed invention. The Examiner never points to any support in Zang or elsewhere in the prior art that a foot bone prosthesis fixed to a vertebra would be able to replace a cephalad portion of a natural facet joint, as required by claim 26. For these reasons, claim 26 is patentable over Zang under § 102(b).

Claim 27 Is Patentable Over Zang

Claim 27 depends from claim 1 and is therefore patentable over Zang for the reasons stated above with respect to claim 1. In addition, claim 27 further limits claim 1 by requiring that the prosthetic facet joint articulating surface be adapted and configured to replace a cephalad portion of a natural facet joint and articulate with a caudal portion of a facet joint of an adjoining vertebra. Once again, the Final Office Action never directly addresses these limitations. At most, the Examiner asserts that the Zang foot bone prosthesis is "structurally similar" to the claimed vertebral facet joint prosthesis "and therefor[e] remains capable of providing the same function" as the claimed invention. The Examiner never points to any support in Zang or elsewhere in the prior art that a foot bone prosthesis fixed to one vertebra would be able to replace a cephalad portion of a natural facet joint, and would be able to articulate with a caudal portion of a facet joint of an adjoining vertebra, as required by claim 27. For these reasons, claim 27 is patentable over Zang under § 102(b).

Claims 5, 6 and 18 Are Patentable Over Zang Alone Or In View of Johnson

Claims 5 and 6 stand rejected as being unpatentable under 35 U.S.C. § 102(b) over Zang. Claims 5, 6 and 18 stand rejected as being unpatentable under 35 U.S.C. § 103(a) over Zang in view of Johnson. Claims 5, 6 and 18 each depend directly from claim 1 and are therefore patentable over Zang for the reasons stated above with respect to claim 1. In addition, claims 5, 6 and 18 add further limitations to claim 1 that are not taught or suggested by Zang, as further explained below. As will

also be explained, Johnson, taken either alone or in combination with Zang, fails to make up for the deficiencies of Zang.

Claim 5 further limits claim 1 by requiring that the prosthetic facet joint articulating surface be removably carried by the fastening element. In briefly addressing claim 5, the Examiner points to "element 70 or 44 of Zang" (Final Office Action at page 3). Element 70 is described by Zang as "a short tang" included on a metatarsal head 20. Col. 9, lines 67-68. Element 44 is described by Zang as "a beveled forward peripheral side surface" of receptacle portion 34. Col. 3, line 67, to col. 4, line 1. The Examiner has not pointed to any teaching or suggestion in Zang that these features would allow a prosthetic facet joint articulating surface to be removable, as required by claim 5. Moreover, nothing in Johnson makes up for this deficiency of Zang. Johnson is concerned with attaching a prosthesis to a tibia and does not appear to even mention an articulating surface, let alone how an articulating surface would be removably carried by a fastening element. For these reasons, claim 5 is patentable over Zang and Johnson.

Claim 6 further limits claim 1 by requiring that the structure be removably attached to the fastening element by frictional engagement. In briefly addressing claim 6, the Examiner points to "element 70 or 44 of Zang" (Final Office Action at page 3). Element 70 is described by Zang as "a short tang" included on a metatarsal head 20. Col. 9, lines 67-68. Element 44 is described by Zang as "a beveled forward peripheral side surface" of receptacle portion 34. Col. 3, line 67, to col. 4, line 1. Again, the Examiner has not pointed to any teaching or suggestion in Zang that these features would allow a structure to be removably attached to the fastening element by frictional engagement, as required by claim 6. Moreover, nothing in Johnson makes up for this deficiency of Zang. Johnson is concerned with attaching a prosthesis to a tibia and does not appear to even mention an articulating surface, let alone how an articulating surface attached to a structure would be removably attached to a fastening element by frictional engagement. For these reasons, claim 6 is patentable over Zang and Johnson.

Claim 18 further limits claim 1 by requiring that the fastening element be fixed to the vertebra by an adhesive or cement. The Examiner implicitly admits that Zang does not teach the use of an adhesive or cement by not rejecting claim 18 as being anticipated by Zang under § 102(b) as with other claims. Instead, the Examiner relies on Johnson as teaching the use of adhesive or cement to fix a fastening element of a facet joint prosthesis to a vertebra (Final Office Action at page 5)..

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The Johnson reference not only does not teach the use of an adhesive or cement, it teaches away from such use by showing and describing a stem that is press fit into the tibia. As shown in Figures 10-12 of Johnson and described at column 5, lines 15-22, a hole is first punched into the bone rather than drilled (presumably to compress the surrounding bone to allow for a better press fit of the stem.) The stem is then driven into the hole as shown. Note in Fig. 11 that the hole in the bone that the stem is driven into is smaller than the diameter of stem cylindrical section 39. "This allows the fins 41 to bite into surrounding bone tissue that is adjacent hole 46". Col. 5, lines 21-22. In describing the method of implanting the device, Johnson does not teach or suggest the use of an adhesive or cement, as required by claim 18. For these reasons, claim 18 is patentable over Zang and Johnson.

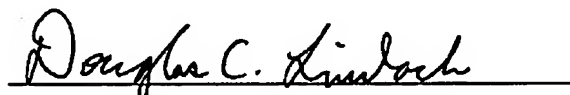
CONCLUSION

For the reasons stated above, claims 1, 2, 4-6, 8, 9, 11-19 and 23-29 are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. § 102(b) and § 103(a) are improper and should be withdrawn. Appellants respectfully ask the Board to overturn the Examiner's rejections with instructions to allow the claims.

The USPTO is directed and authorized to charge all required fees to Deposit Account No. 50-4050.

Respectfully submitted,

Date: May 23, 2007



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VIII. CLAIMS APPENDIX

1. A prosthesis to replace all or a portion of a natural facet joint on a vertebra, comprising:

a fastening element adapted to be removably attached to the vertebra;

a structure removably attached to the fastening element; and

a prosthetic facet joint articulating surface dimensioned to replace all or a portion of a natural facet joint on the vertebra wherein the prosthetic facet joint articulating surface removably attaches to the structure.
2. A prosthesis according to claim 1 wherein the structure is fixed to the fastening element.
3. *(Withdrawn)* A prosthesis according to claim 1 wherein the structure is fixed to the fastening element by an adhesive or cement.
4. A prosthesis according to claim 1 wherein the structure is fixed to the fastening element by mechanical attachment.
5. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is removably carried by the fastening element.
6. A prosthesis according to claim 1 wherein the structure is removably attached to the fastening element by frictional engagement.
7. *(Withdrawn)* A prosthesis according to claim 1 wherein the structure is removably attached to the fastening element by a Morse taper.
8. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface comprises an insert fitted to the structure.

9. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface comprises an insert fitted by frictional engagement to the structure.
10. *(Withdrawn)* A prosthesis according to claim 1 wherein the artificial facet joint structure comprises an insert fitted by a Morse taper to the fastening element.
11. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface comprises a removable insert fitted to the structure.
12. A prosthesis according to claim 1 wherein the structure pivots with respect to the fastening element.
13. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is adapted and configured to articulate with a portion of a facet joint of an adjoining vertebra.
14. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is adapted and configured to replace a caudal portion of a natural facet joint.
15. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is adapted and configured to replace a caudal portion of a natural facet joint and articulate with a cephalad portion of a facet joint of an adjoining vertebra.
16. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is made of at least one selected prosthetic material.
17. A prosthesis according to claim 16 wherein the selected prosthetic material includes polyethylene, rubber, tantalum, titanium, chrome cobalt, surgical steel, bony in-growth material, ceramic, artificial bone, or a combination thereof.
18. A prosthesis according to claim 1 wherein the fastening element is fixed to the vertebra by an adhesive or cement.
19. A prosthesis according to claim 1 wherein the fastening element includes a bony in-growth material.

20. *(Withdrawn)* A method of replacing, on a vertebral body, all or a portion of a natural facet joint using the prosthesis defined in claim 1 to provide improved support for the spinal column, the method comprising the steps of

(i) removing all or a portion of a natural articular process from the vertebral body, and

(ii) fixing the prosthesis as defined in claim 1 to the vertebral body to replace the removed portion of the natural articular process with the artificial facet joint structure.

21. *(Withdrawn)* A method according to claim 20 further including a step of removing at least some of the lamina from the vertebral body.

22. *(Withdrawn)* A method according to claim 20 further including a step of removing at least part of a pedicle from the vertebral body.

23. A prosthesis according to claim 1 wherein the structure is fixed to the prosthetic facet joint articulating surface.

24. A prosthesis according to claim 1 wherein the fastening element is to the vertebra at or near a pedicle.

25. A prosthesis according to claim 1 wherein the fastening element is to the vertebra at a location away from a pedicle.

26. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is adapted and configured to replace a cephalad portion of a natural facet joint.

27. A prosthesis according to claim 1 wherein the prosthetic facet joint articulating surface is adapted and configured to replace a cephalad portion of a natural facet joint and articulate with a caudal portion of a facet joint of an adjoining vertebra.

28. A prosthesis according to claim 1 wherein the fastening element is made of at least one selected prosthetic material.

29. A prosthesis according to claim 28 wherein the selected prosthetic material includes prosthetic materials selected from the group consisting of polyethylene, rubber, tantalum, titanium, chrome cobalt, surgical steel, bony in-growth material, ceramic, artificial bone, or a combination thereof.

IX. EVIDENCE APPENDIX

U.S. Patent 5,314,486 (Zang et al.) cited by Examiner in office action mailed on 08/23/2006.

U.S. Patent 5,609,641 (Johnson et al.) cited by Examiner in office action mailed 08/23/2006.

X. RELATED PROCEEDINGS APPENDIX

None.